REMARKS

Claims 1,2,6-10,12,13,16-18 and 21-44 are pending.

The present amendment cancels Claims 1,2,6-10,12,13,16-18 and 21-44 and adds new Claims 45 to 60.

Applicants reserve the right to file continuation applications with claims directed to the subject matter of cancelled Claims 1,2,6-10,12,13,16-18 and 21-44.

* * *

I. Cancelled Claims 1,2,6-10,12,13,16-18 and 21-44 and New Claims 45-60

Applicants have cancelled pending Claims 1,2,6-10,12,13, 16-18 and 21-44 and added new Claims 45 to 60. The added claims are generically embraced by cancelled Claim 1, but further clarify the claimed subject matter.

Specifically, the two pending independent claims after the present amendment (Claims 45 and 52) now provide that:

(a) the epoxy-steroidal aldosterone receptor antagonist of the composition or method is eplerenone, present or administered in an amount from about 1 mg to about 400 mg,

(b) the ACE inhibitor of the composition or method is ramipril, present or administered in an amount from about 1 mg to about 200 mg, and

(c) the loop diuretic of the composition or method is present or administered in an amount from about 1 mg to about 200 mg.

Support for new Claims 45-60 is found, for example, in prior pending Claims 1-44 and in the specification, as follows:

New Claims 45-60	**Prior Pending Claims 1-44**	**Specification Page(s)/Line(s)**
45	1,31	P.20,L.20-24;P.31,L.20-35
46	23	P.22,L.28-30
47	--	P.31,L.20-35
48	--	P.40,L.12-13
49	--	P.31,L.20-35
50	--	P.20,L.20-24
51	1,31	P.20,L.20-24;P.31,L.20-35
52	9,31	P.20,L.20-24;P.31,L.20-35
53	23	P.22,L.28-30
54	--	P.31,L.20-35
55	--	P.40,L.12-13
56	--	P.31,L.20-35
57	--	P.20,L.20-24
58	1,31	P.20,L.20-24;P.31,L.20-35
59	12	P.31,L.1-7
60	13	P.31,L.1-7

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II. Rejection Under 35 USC §103(a) over WO 96/40257, Jondeau et al. and Dahlstrom et al.

The Office has rejected pending Claims 1, 2, 6-10, 12, 13, 16-18, 21-23, 30, 34 and 41 under 35 USC §103(a) as being unpatentable over WO 96/40257 ("'257 Application"), Jondeau et al. (Am. J. Cardiol., 1996; 79: 635-638) ("Jondeau") and Dahlstrom et al. (Am. J. Cardiol., 1993; 71(3): 29A-33A) ("Dahlstrom"). Applicants respectfully disagree and request withdrawal of this rejection.

It is well accepted (e.g., MPEP §2142) that in order to establish a prima facie case of obviousness the Office must show:

(1) there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings,

(2) there is a reasonable expectation of success if the modification or combination is carried out, and

(3) the reference, or references when combined, teach or suggest all the claim limitations.

Further, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants' disclosure.

As previously noted, Applicants have cancelled pending Claims 1,2,6-10,12,13, 16-18 and 21-44 and added new Claims 45 to 60. Also, as previously noted, the two pending independent claims after the present amendment (Claims 45 and 52) now provide that:

(a) the epoxy-steroidal aldosterone receptor antagonist of the composition or method is eplerenone, present or administered in an amount from about 1 mg to about 400 mg,

(b) the ACE inhibitor of the composition or method is ramipril, present or administered in an amount from about 1 mg to about 200 mg, and

(c) the loop diuretic of the composition or method is present or administered in an amount from about 1 mg to about 200 mg.

Jondeau describes a study where quinapril was administered, either alone or in combination with a loop diuretic, digoxin or a nitrate, to a small group of patients having congestive heart failure. Jondeau does not disclose or suggest using eplerenone or any aldosterone antagonist in such therapy. It further

focuses on the ACE inhibitor quinapril and does not reference the compound ramipril. In addition, it fails to disclose or suggest combining eplerenone, ramipril and loop diuretic in a pharmaceutical composition or treatment regimen, either generally or at the specific amounts recited in the claims.

Likewise, Dahlstrom describes a study that reported "that rational therapy includes addition of the aldosterone antagonist spironolactone to low doses of captopril (or another ACE inhibitor) and high doses of loop diuretics, provided renal function is adequate" for patients having congestive heart failure. Dahlstrom does not disclose or suggest using eplerenone as the aldosterone antagonist in such therapy. It further focuses on the ACE inhibitor captopril and does not reference the compound ramipril. In addition, it fails to disclose or suggest combining eplerenone, ramipril and loop diuretic in a pharmaceutical composition or treatment regimen, either generally or at the specific amounts recited in the claims.

Finally, the '257 Application also fails to disclose or suggest using eplerenone, ramipril, and loop diuretic in a pharmaceutical composition or treatment regimen, either generally or at the specific amounts recited in the claims. The '257 Application is actually directed to a combination of an epoxy-steroidal aldosterone antagonist and an angiotensin II receptor antagonist. An angiotensin receptor II antagonist is from an entirely different drug class than an ACE inhibitor (i.e., an angiotensin converting enzyme inhibitor).

Therefore the three references cited by the Office, either alone or in combination, do not teach or suggest the Applicants' invention as claimed in new Claims 45-60.

Accordingly, the aforementioned §103 objection should not be maintained against new pending Claims 45-60.

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Applicants' new Claims 45-60 should now be in condition for allowance.

Favorable consideration and early allowance of pending claims 45-60 is requested. Applicants respectfully request a three-month extension of time to and including December 6, 2005 for filing a response to the June 6, 2005 Office Action in this matter. The Commissioner is hereby authorized to charge the $1020.00 fee for the requested three-month extension of time under 37 C.F.R. 1.16 and 1.17, together with any fees that may be required during the entire pendency of this application, to Deposit Account No. 19-1025.

Respectfully submitted,

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